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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
09/148,012	09/04/98	KRIEGER	M 011/15001P

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HM22/0316

EXAMINER
LANDSMAN, R

ART UNIT	PAPER NUMBER
1646	7

DATE MAILED: 03/16/00

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

file copy

Office Action Summary	Application No. 09/148,012	Applicant(s) KRIEGER, MONTY	
	Examiner Robert Landsman	Art Unit 1646	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).

Status

- 1) ☒ Responsive to communication(s) filed on 19 April 1999.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☐ Claim(s) 1-18 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-18 is/are rejected.
- 7) ☐ Claim(s) 8-14 and 17 is/are objected to.
- 8) ☐ Claims _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are objected to by the Examiner.
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved.
- 12) ☒ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).
- a) ☐ All b) ☐ Some * c) ☐ None of the CERTIFIED copies of the priority documents have been:
1. ☐ received.
2. ☐ received in Application No. (Series Code / Serial Number) _____.
3. ☐ received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. & 119(e).

Attachment(s)

- | | |
|---|--|
| 14) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 17) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____ |
| 15) <input checked="" type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 18) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 16) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) <u>6</u> . | 19) <input type="checkbox"/> Other: _____ |

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DETAILED ACTION

- A. The IDS, filed on 4/19/99, has been entered into the record.

1. Oath/Declaration

- B. The Declaration is objected to since it is not clear if the zip code for Monty Krieger is correct. Please clarify the zip code or send a new Declaration.

2. Specification

- C. The Specification is objected to since:

Various Figures are labeled with capital letters after the figure number, but in the Brief Description of Drawings, lower case letters are used. Appropriate correction is required.

On page 10, line 22, the phrase should be separated by commas to read "...to show that, upon estrogen treatment in rats, levels of SR-BI..."

3. Claim Rejections - 35 USC § 112, second paragraph

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

- D. Claim 17 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. This claim is confusing. The claim is drawn to a method of *manufacturing* a compound wherein the compound is obtained by *screening* for binding. It is not understood how one can manufacture a compound simply by screening for its ability to bind a protein. No method steps are recited of how to

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manufacture a compound. There are various types of compounds and the methods for producing them vary greatly.

In addition, the phrase "obtained by screening for binding to or alteration of activity of SR-BI in binding or transfer of cholesterol or cholesteryl ester" is confusing. The syntax could be improved by rewording this part of the claim as "obtained by binding to SR-BI, or by altering the ability of SR-BI to mediate *said* transfer cholesterol or cholesteryl ester. However, this claim is still confusing since it is not known if the compound obtained alters SR-BI activity directly or indirectly.

4. Claim Rejections - 35 USC § 112, first paragraph – enablement

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

E. Claim 17 is rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

Claim 17 encompasses subject matter which was not described in the specification. The claim is drawn to a method of *manufacturing* a compound wherein the compound is obtained by *screening* for binding. It is not understood how one can manufacture a compound simply by screening for its ability to bind a protein. There is a lack of written description with regard to what the test compound is, or how to produce said test compound. First, it is not clear if the compound is a peptide or non-peptide. If it is a peptide it could be a naturally occurring peptide, or non-naturally occurring peptide synthesized by the

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hand of man. If it is a non-peptide compound it could be, for example, a sugar, or a fatty acid. It could also be a synthetic organic compound such as benzene, or an inorganic synthesized compound such as various acids or salts. Clearly, various methods for producing these types of compounds are known in the art and the breadth of this claim is too large with regard to claiming *every* method for producing a compound.

5. Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

F. Claims 1-7, 15, 16 and 18 are rejected under 35 U.S.C. 102(a) as being unpatentable over Rigotti et al (6/97). The claims are drawn to a method of modifying steroid production in a mammal by administering a compound which alters the transfer of cholesterol to liver or steroidogenic tissues via SR-BI. Rigotti et al. teach a method of modifying steroid production in a mammal comprising administering a compound which alters the transfer of cholesterol from HDL to steroidogenic tissue (page 181, right column, paragraph 3 and page 183, right column, second paragraph) Rigotti et al. also teach (page 183, left column, bottom paragraph) that SR-BI is primarily expressed on the surfaces of steroidogenic cells and that SR-BI mediates the transfer of cholesteryl esters to supply substrate for steroid hormone synthesis (page 183, right column, second paragraph). Rigotti et al. also teach that various compounds alter this transfer by altering the expression of SR-BI in these tissues, either by increasing or decreasing

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the expression (page 183, right column, second paragraph). This change in receptor expression would lead to an increase or decrease in the binding of SR-BI to HDL.

Finally, Rigotti et al. teach that estrogen differentially alters the expression of SR-BI in different tissues since it increases expression in the ovary and decreases expression in the liver (page 183, column 2, second paragraph). These compounds were administered *in vivo* and are, therefore, considered pharmaceutical compositions (page 183, column 2). Therefore, it would be inherent that compounds altering the transfer of cholesterol or cholesteryl ester from HDL or other lipoproteins to the liver or steroidogenic tissues would act via SR-BI. Claims 8-14¹⁷ and ~~16~~ are objected to since they depend from rejected base claims.

G. Claim 8 is rejected under 35 U.S.C. 102(b) as being unpatentable by Spona et al. (1996). The claim is directed to a method for modifying steroid production to prevent normal reproductive function in a female mammal by altering SR-BI activity. Spona et al. teach that administration of steroids (page 300, "Materials and Methods" under "Study Design") in females who had normal ovulatory cycles (page 300, "Materials and Methods" under "Volunteers") inhibited ovulation (page 303, Discussion, first paragraph). It is inherent that the steroids are inhibiting normal reproductive function by modulating SR-BI to alter cholesterol uptake by steroidogenic cells even though SR-BI modulation is not taught in the prior art.

H. Claims 9, 12 and 13 are rejected under 35 U.S.C. 102(b) as being unpatentable by Bajetta et. al. (1994). The claims are directed to a method for decreasing the overproduction of steroids via modulation of SR-BI where the disorder may be breast cancer. Bajetta et. al. teach that formestane, is a selective inhibitor of aromatase, which is responsible for estrogen synthesis (see Abstract). They also teach that administration of formestane to women with breast cancer significantly reduced plasma estrogen levels

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(Abstract). Finally, they teach a significant remission in breast cancer by treatment with two different doses of formestane (page 147, right column, first paragraph and Table II). Therefore, it has been shown that breast cancer is associated with an overproduction of estrogen.

I. Claims 9, 12 and 14 are rejected under 35 U.S.C. 102(b) as being unpatentable by Cirkel. The claims are directed to decreasing the overproduction of steroids in which the disorder is endometriosis. Cirkel teaches that continuous application of progestogens will lead to a hypo-estrogenic endocrine environment causing initial decidualization of endometrial tissues with eventual atrophy (see page 93 under "Progestogens and endometriosis"). It is inherent that the steroids are inhibiting the overproduction of steroids in endometriosis by modulating SR-BI to alter cholesterol uptake by steroidogenic cells even though SR-BI modulation is not taught in the prior art.

J. Claims 10 and 11 are rejected under 35 U.S.C. 102(b) as being unpatentable by Whitcroft and Stevenson (1992). The claims are directed to a method of modifying steroid production via SR-BI wherein the mammal has a disorder characterized by the underproduction of steroids and in which the disorder may be menopause. Whitcroft and Stevenson discuss hormone replacement therapy in which the administration of steroids to menopausal women is used to prevent the long-term consequences of estrogen deficiency (see Abstract and page 15, second column, final full paragraph). Because the Applicant is also treating the patient with steroids, the treatment must be accomplished inherently through the same modulation of SR-BI.

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Advisory information

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Robert Landsman whose telephone number is (703) 306-3407. The examiner can normally be reached on Monday - Friday from 8:00 AM to 5:00 PM (Eastern time) and alternate Fridays from 8:00 AM to 5:00 PM (Eastern time).

If attempts to reach the examiner by telephone are unsuccessful, the Examiner's supervisor, Gary Kunz, can be reached on (703) 308-4623.

Official papers filed by fax should be directed to (703) 308-4242. Fax draft or informal communications with the examiner should be directed to (703) 308-0294.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.

Robert Landsman, Ph.D.
Patent Examiner
Group 1600
March 13, 2000

Gary L. Kunz
GARY L. KUNZ
PRIMARY EXAMINER
GROUP 1200